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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,428	10/15/2001	Peter Unger	B0048-US02	5257
24994	7590	05/27/2004	EXAMINER	
GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,428

Applicant(s)

UNGER ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 6-11 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,114,396 (hereinafter referred to as Unger et al). Unger et al teach a method of separating cells in a centrifuge comprising providing blood e.g. cell suspension in a processing bag (2), separating cell suspension in the processing bag (2) into blood cells and plasma by centrifugation, transferring plasma to a storage bag (32) via an outlet tube (10, 31) in a position having a radially inwardly directed flow and having a centrifugal valve (22) associated therewith whereby the processing bag (2), the storage bag (32), the outlet tube (10) and the centrifuge valve (22) are all disposed in the rotating part of the centrifuge during centrifugation whereby the step of transferring plasma through the outlet tube (10) occurs upon activation of the centrifuge valve (22) into open position during centrifugation (figures 1-5, 6; col. 2, line 65 – col. 7, line 13).

3. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,116,308 (hereinafter referred to as Hagiwara et al). Unger et al teaches a centrifugally actuated pinch valve (22) (see col. 7, lines 7-12). Hagiwara et al teach the use of manually clamp (41) or electromagnetic valve (41) which is well-known in the art to control the flow of the fluid in an outlet tube from a blood treatment apparatus (see 41 in Figure 2; col. 10, lines 11-25). It would have been obvious to a person of ordinary skill in the art to substitute well-known manually activatable clamp or

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magnetically activatable valve or electromagnetically activatable valve for a centrifugally activated valve in the outlet tube in the method of Unger et al to control the flow of enriched fraction to a storage bag.

4. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842 in view of Unger et al. WO95/01842 teaches a method of separating cells in a centrifuge comprising providing buffy coat in a processing bag (1) in a centrifuge, separating buffy coat into thrombocyte-rich plasma (i.e. light-weight fraction enriched with platelets), transferring thrombocyte-rich plasma to a storage bag (2) via an outlet tube (3) in a position having a radially inwardly and outwardly directed flow and having an opened clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (3) wherein buffy coat inherently includes platelets and red blood cells whereby the processing bag (1), the storage bag (2), the outlet tube (3) and valve (38) are all disposed in a rotating part of the centrifuge (see figures 5-8; page 8, line 29 - page 10, line 31). Claims 1-3 and 6-8 essentially differ from the method of WO95/01842 in reciting that activation of valve into open position during centrifugation. Unger et al teach the method of separating cells as described in above paragraph
2. Unger et al further teach that centrifugally activated valve (22) is held in a closed position when a cell suspension is fed into the processing bag (2) e.g. primary container and the valve (22) is opened upon centrifugation to transfer plasma fraction to a storage bag (32) (see col. 7, lines 7-12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to activate clamp valve into an open position from a closed position during

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on-going centrifugation to transfer thrombocyte-rich plasma from a processing bag (1) to a storage bag (2) in WO 95/01842 during centrifugation.

5. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842 as applied to claim 1 above, and further in view of U.S. Patent No. 5,116,308 (hereinafter referred to as Hagiwara et al). WO95/01842 teaches clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (see page 9, lines 4-11). Hagiwara et al teach the use of manually clamp (41) or electromagnetic valve (41) which is well-known in the art to control the flow of the fluid in an outlet tube from a blood treatment apparatus (see 41 in Figure 2; col. 10, lines 11-25). It would have been obvious to a person of ordinary skill in the art to substitute well-known manually activatable clamp or magnetically activatable valve or electromagnetically activatable valve for a valve in the outlet tube in the method of WO95/01842 to control the flow of enriched fraction to a storage bag.

6. Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


7. Applicant's arguments with respect to claims 1 and 3-11 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John Kim
Primary Examiner
Art Unit 1723

J. Kim
May 25, 2004